FDA 510(k) Premarket Notification

K936010 THYROGLOBULIN AUTOANTIBODY ENZYME IMMUNOASSAY

CLEARED

Jul 18, 1994
214 days to decision

K936010 · Product code: **DDC** · Immunology
Source: https://www.510kdatabase.net/k936010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thyroglobulin, Antigen, Antiserum, Control (DDC)
Date received	Dec 16, 1993
Decision date	Jul 18, 1994
Days to decision	214 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Biomerica, Inc.**
Location	Newport Beach, CA, US
Contact	PERRY G RUCKER
Website	http://www.biomerica.com
510(k) history	10 submissions · 10 cleared · 1991-2023

Biomerica, Inc. is a global biomedical technology company developing, manufacturing, and marketing advanced in-vitro diagnostic products. Headquartered in Irvine, California, the company operates FDA and CE registered manufacturing facilities in California and Mexico, specializing in gastrointestinal and inflammatory disease diagnostics. Biomerica has received FDA 510(k) clearances from total submissions since 1991. The company's cleared devices span chemistry, microbiology, and immunology categories, including pregnancy tests, thyroid function assays, H. pylori detection...